K011355

JAN 17 2002

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Biolight International AB summary for the Biolight PCD (referred to as the Biolight CPS, Biolight WCD or 7025 Multidiod in the attached engineering documents).

SUBMITTER'S NAME: Biolight International AB
ADDRESS: Svardvagen 15
S-18233 Danderyd
Sweden

CONTACT PERSON: Constance Bundy
TELEPHONE NUMBER: 763-574-1976
FAX NUMBER: 763-571-2437

DATE OF SUBMISSION: May 1, 2001

1. **Identification of device**
   Proprietary Name: Biolight PCD
   Classification Status: This device is classified as an Infrared Lamp, Class II per regulation 890.5500.
   Product Codes: ILY

2. **Equivalent devices**
   Biolight International AB believes that the Biolight PCD is substantially equivalent to the Super-Nova (K001179) marketed by Light Force Therapy, Inc.

3. **Description of the Device**
   The Biolight PCD consists of a hand unit that delivers infrared light therapy in accordance with a pre-programmed treatment card.

   The hand unit consists of a plate with light emitting diodes for generating infrared and red light, a motor and machinery for diode rotation, and electronic components for control and communication. This hand unit also has a treatment card connection through which the micro control unit can communicate with the pre-programmed treatment cards, which contain information about the number of treatments and the parameters for each separate type of treatment. The hand unit is connected to the power pack through a cable, which can be plugged into the hand unit.

   The power pack consists of a standard battery eliminator, which through a transformer and a rectifier provides 12 V DC for powering the hand unit.

   The manufacturer creates the pre-programmed treatment cards by using the Administrative Tool System. This software system is used with a personal computer to program the treatment cards with the appropriate therapy parameters.

4. **Intended use**
The Biolight PCD is a portable instrument intended to provide infrared light therapy to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue.

5. **Technological characteristics**
The Biolight PCD is similar in design and function, safety and effectiveness, and indications for use to the predicate system identified above. Both are similar in intended use and operation, are software controlled and comply with appropriate standards.

6. **Discussion of performance testing.**
An extensive collection of tests have been conducted and successfully completed on the Biolight PCD, including software verification/validation, system testing, conformance to all relevant requirements of the IEC 601 series of electrical standards and an animal safety study.

7. **Conclusion**
It is the conclusion of Biolight International AB that the Biolight PCD is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biolight International AB
C/O Constance G. Bundy
C.G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432

JAN 17 2002

Re: K011355
Trade/Device Name: Biolight PCD
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: October 18, 2001
Received: October 22, 2001

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus; permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE

510(k) Number K011355

Device Name: Biolight PCD

Indications for Use:

The Biolight PCD is a portable instrument intended to provide infrared light therapy to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness and promoting relaxation of muscle tissue. The Biolight PCD consists of a hand unit with diodes that delivers the light therapy in accordance with a pre-programmed treatment card.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011355/S1